平成29年9月4日

日本学術振興会
プロセスシステム工学第143委員会
委員長　山下　善之

# プロセスシステム工学第143委員会

## 特別シンポジウム 開催通知（案）

（143委員会ホームページ http://www.pse143.org/）

１．日　　時：2017年10月23日（月）13：00～17：00

２．場　　所：エムワイ貸会議室お茶の水

（東京都千代田区神田駿河台2-1-20お茶の水ユニオンビル 4F　／電話：0120-311-104）
（交通：JR 中央線・総武線「御茶ノ水」駅 御茶ノ水橋口 徒歩 2 分）
http://meijiyasuda-life-hall.com/kashikaigishitsu-ochanomizu/index.html

３．シンポジウム　　“医薬品の連続製造とプロセスシステム工学 /
Continuous manufacturing of pharmaceuticals and PSE“

趣旨：医薬品は従来、バッチ式プロセスで製造されてきたが、これを連続式で製造する動きが盛んになっている。本シンポジウムでは、本テーマの専門家である米国Rutgers大学のMarianthi Ierapetritou教授を招へいし、最新の研究動向に関する知見を得るとともに、国内の関係研究者の講演とディスカッションを通してプロセスシステム工学としての展開を考える。

13:00～13:10 特別シンポジウム趣旨説明 / Introduction of the symposium

13:10～14:10 **Continuous Pharmaceutical Manufacturing: Challenges and Opportunities**
Prof. Marianthi Ierapetritou (Rutgers University)
**Abstract:**
The pharmaceutical supply chain is slow compared to other chemical processing industries. Breakthrough technologies such as combinatorial chemistry and high-throughput screening have helped expedite the discovery portion of the pharmaceutical production process but the remainder of the drug development and manufacturing process often lags behind. A potential solution, which has been gaining momentum in the pharmaceutical field and may help speed the manufacturing portion of the production chain is continuous manufacturing.

The numerous advantages of continuous manufacturing over batch processing include superior process control, lower inventory requirements, easier scale-up, and steady state dynamics. Much work remains to be done, however, before the pharmaceutical industry, as a whole is able to shift away from traditional batch manufacturing process, as the implementation of continuously manufacturing at the industrial scale is still at the beginning. A review of the progress done in this front in the last decade would be covered in this talk together with the challenges involved in this implementation.

14:10～14:50 **Development of stable real-time monitoring method for pharmaceutical continuous manufacturing**
Ms. Yuki Hasegawa & Dr. Hiroshi Nakagawea (Daiichi Sankyo Co., Ltd.)
**Abstract:**
It is important to perform stable real-time process monitoring in pharmaceutical continuous manufacturing in order to assure the product quality. Near-infrared (NIR) is generally used for the purpose, but the monitoring method should be carefully verified to achieve the good prediction accuracy. We developed the stable monitoring methods for continuous tableting and coating processes by devising the probe install position and

equipment design: the probe was installed to the bottom part of feeder in the tablet press and the diagonal type coating pan was applied to enable the constant monitoring without any interferences. The monitoring results demonstrated to elucidate the residence time distribution (RTD) in the tableting process precisely and to determine the endpoint of the coating process reliably.

14:50～15:10 休憩 / Break

15:10～15:50 **“CTS-MiGRA-System” A continuous-manufacturing system for solid dosage forms**
Mr. Takuya Nagato (Powrex Corporation)
**Abstract:**
We have developed “CTS-MiGRA-System,” a continuous-manufacturing system for solid dosage forms. This system enables integrated manufacturing that includes raw material powder handling and tablet coating processes, featuring the function to achieve granules with uniform particle size distribution so that they are suitable for tableting or other processes. This system consists of powder-mixing, granulating, drying, sieving, tableting and coating in each process. Each process incorporates PAT Technology by which critical quality attributes are continuously monitored to ensure real time release of final products.

15:50～16:30 **Data-driven process modeling method: a tool for PAT**
Assist. Prof. Sanghong Kim (Kyoto University)
**Abstract:**
Data-driven process modeling enables us to have real-time estimates of difficult-to-measure variables such as critical quality attributes (CQA), by using the measurements of easy-to-measure variables. Thus, data-driven method can be important part of process analytical technology (PAT). In this presentation, the basic procedure of data-driven process modeling is explained, and application examples of the data-driven model developed by the presenter in a pharmaceutical and a chemical process are introduced. Then, the data-driven process modeling methods used in pharmaceutical processes are summarized, and the future direction is discussed.

16:30～17:00 Discussion

＜追記＞
準備の都合がありますので，出欠を１０月６日（金）までに下記HPにてご回答下さい.

URL https://reg31.smp.ne.jp/regist/is?SMPFORM=lgma-sjljq-f2264752af6a1424ab073bb2c27850cd

問い合わせ先：日本学術振興会
船田雅美（E-mail：jigyouka04@jsps.go.jp，Tel:03-3263-1728）